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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,059	07/22/2003	Richard G. Wilde	10589-015-999	8259
20583	7590	04/14/2006	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017				OLSON, ERIC
		ART UNIT		PAPER NUMBER
		1623		

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/625,059	WILDE ET AL.	
	<b>Examiner</b> Eric S. Olson	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 22 July 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-28 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

**Detailed Action**

This application claims benefit of provisional application 60/398334, filed July 24, 2002. Claims 1-18 are pending in this application.

**Election/Restriction**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19 in part, drawn to a method of treating or preventing a disease resulting from a somatic mutation involving a compound of formula I in which X represents oxygen or sulfur, classified in class 514, subclass 42 or 43, for example.
- II. Claims 1-19 in part, drawn to a method of treating or preventing a disease resulting from a somatic mutation involving a compound of formula I in which X represents NH, classified in class 514, subclass 42 or 43, for example.
- III. Claims 1-19 in part, drawn to a method of treating or preventing a disease resulting from a somatic mutation involving a compound of formula I in which X represents CH<sub>2</sub>, classified in class 514, subclass 42 or 43, for example.
- IV. Claims 20-25 in part, drawn to a compound having a structure described by formula II, in which X represents oxygen or sulfur, and both A and B represent carbon, classified in class 514, subclass 42, for example.

- V. Claims 20-25 in part, drawn to a compound having a structure described by formula II, in which X represents NH, and both A and B represent carbon, classified in class 514, subclass 42, for example.
- VI. Claims 20-25 in part, drawn to a compound having a structure described by formula II, in which X represents  $\text{CH}_2$ , and both A and B represent carbon, classified in class 514, subclass 42, for example.
- VII. Claims 20-25 and 28, in part, drawn to a compound having a structure described by formula II, in which X represents oxygen or sulfur, and exactly one of A or B represents nitrogen, classified in class 514, subclass 43, for example.
- VIII. Claims 20-25 and 28, in part, drawn to a compound having a structure described by formula II, in which X represents NH, and exactly one of A or B represents nitrogen, classified in class 514, subclass 43, for example.
- IX. Claims 20-25 and 28, in part, drawn to a compound having a structure described by formula II, in which X represents  $\text{CH}_2$ , and exactly one of A or B represents nitrogen, classified in class 514, subclass 43, for example.
- X. Claims 20-28 in part, drawn to a compound having a structure described by formula II, in which X represents sulfur or oxygen, and A and B both represent nitrogen, classified in class 514, subclass 43, for example.
- XI. Claims 20-26 and 28, in part, drawn to a compound having a structure described by formula II, in which X represents NH, and A and B both represent nitrogen, classified in class 514, subclass 43, for example.

XII. Claims 20-26 and 28, in part, drawn to a compound having a structure described by formula II, in which X represents  $\text{CH}_2$ , and A and B both represent nitrogen, classified in class 514, subclass 43, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I -III are directed to related methods of treating disease. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the presence of a nitrogen or chalcogen in the X position of the chemical structure is expected to be significant in establishing the properties and uses of the compounds. A reference anticipating or rendering obvious one member will not anticipate or render another obvious.

Chemical structures which are similar are presumed to function similarly, while chemical structures which are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention.

Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2s 381, 137 USPQ 43 (CCPA 1963), and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where structures are either not

structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Therefore, a chemical structure or name search for more than one of the aforementioned groups in a single application would be unreasonably broad and would require separate searches of the chemical literature for each group and impose an undue search burden on the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as recognized by their different classifications, restriction for examination purposes as indicated is proper.

Inventions IV-XII are directed to related compounds. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, In the instant case, the inventions are structurally distinct nucleotides encompassing a range of structures. In particular, the nucleotide base portion of the molecule is a strong determinant of biological activity, and compounds with variation at this position are likely to vary considerably in their mode of operation, function, or effect.

Chemical structures which are similar are presumed to function similarly, while chemical structures which are not similar are not presumed to function similarly. The

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presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention.

Note that in accordance with the holding of *Application of Papesch*, 50 CCPA 1084, 315 F.2s 381, 137 USPQ 43 (CCPA 1963), and *In re Lalu*, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Therefore, a reference anticipating or rendering obvious one member will not anticipate or render another obvious. A chemical structure or name search for more than one of the aforementioned groups in a single application would be unreasonably broad and would require separate searches of the chemical literature for each group and impose an undue search burden on the Office.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter as recognized by their different classifications, restriction for examination purposes as indicated is proper.

Inventions I-III and IV-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

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process of using that product (MPEP § 806.05(h)). In the instant case the method of claim V could be practiced with another materially different product, such as doxorubicin, cyclophosphamide, or other well-known chemotherapeutic agents for the treatment of cancer.

The search field for a composition is non-coextensive with the search field for a method of treating a patient employing the same composition. A reference to the composition herein would not necessarily be a reference to the method of treatment herein under 35 USC 103 because a search indicating the process or method is novel or unobvious would not extend to a holding that the product is novel or unobvious whereas a search indicating that the product is known or would have been obvious would not extend to a holding that the process or method is known and would have been obvious. Note that the search is not limited to patent files. Thus an undue burden on the Office is seen for the search of all inventions herein, as discussed in the Requirement for Restriction above.

Because these inventions are distinct for the reasons given above and the search required for Groups IV-XII is not required for Groups I-III, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

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whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### **Election of Species**

This application contains claims directed to the following patentably distinct species:

- 1) a plurality of disclosed patentably distinct compounds in groups I-XII (See the above restriction requirement); and
- 2) a plurality of disclosed patentably distinct diseases or conditions to be treated in groups I-III (See the above restriction requirement),

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-19 are generic to a plurality of disclosed patentably distinct species (compounds) and diseases to be treated. The

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I-XII

claims of groups ~~III~~ read on the employment of various compounds with great diversity of chemical structure and methods of treatment of unspecified diseases to be treated, the search for all of which presents an undue burden on the Office. It is noted that a reference to one compound or disease would not be a reference to another compound or disease under 35 USC 103.

A "specie" is a specific compound and a specific disease or condition to be treated, with all parameters and/or substituent variables FULLY accounted for.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 USC 103(a) of the other invention.

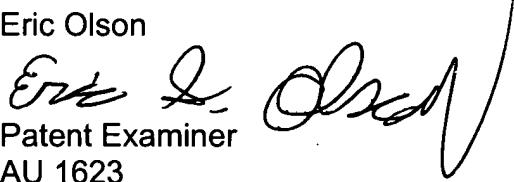
Because the above election/restriction requirement is complex, a telephone call to applicant's agent to request an oral election was not made. (See MPEP 812.01)

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday through Friday from 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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